

100-1524

7/18/2014

1/15

JUL 18 2014

Mr. Patrick McCain  
Senior Regulatory Product Manager – Seed Care  
Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, NC 27419-8300

Re: Syngenta Crop Protection, LLC; SOYACYST™ ST Plus  
EPA Registration No. 100-1524  
Minor Label (“Fast Track”) Amendment  
Submissions Dated 06/12/2014 and 07/11/2014  
Decision No. 492547

Dear Mr. McCain:

The U.S. Environmental Protection Agency (EPA) reviewed your request to amend the subject product registration, which included the following changes to the product label:

- 1) Correction of minor formatting inconsistencies and typographical errors.
- 2) Removal of all on-farm seed treatment application instructions in the Directions for Use.
- 3) Addition of the following statement to the Directions for Use to show that this pesticide product is only to be used in commercial seed treatment facilities and that it is outside the scope of the Worker Protection Standard:

“For use only in commercial seed treatment equipment. Not for use in hopper box, planter box, slurry box, or other on-farm seed treatment applications.”

- 4) Removal of the following text/information from the label, given that this pesticide product is now outside the scope of the Worker Protection Standard:
  - a. Worker Protection Standard Required Statements in the Directions for Use.
  - b. Agricultural Use Requirements Box.
  - c. Non-agricultural Use Requirements Box, except for this statement: “Keep unprotected persons out of treatment areas until seeds have dried or been packaged.”
  - d. Agricultural Use Requirements Referral Statement.

CONCURRENCES

SYMBOL	7511P	7511P	7511P					
USERNAME	KAUSCH	Borges	Uchi					
DATE	07/16/2014	7/16/14	7/18/14					

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Patrick McCain  
EPA Registration No. 100-1524

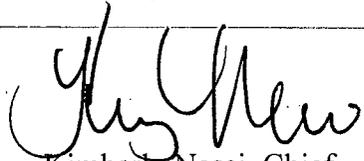
- 5) Addition of Container Handling Instructions (Storage and Disposal Box) and information related to placement of the Batch Code for refillable containers greater than 5 gallons.

All the changes referred to above, submitted in connection with registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable provided that you submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description of final printed labeling.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any questions regarding this letter, please contact Ms. Jeannine Kausch of my staff by telephone (703-347-8920) or email ([kausch.jeannine@epa.gov](mailto:kausch.jeannine@epa.gov)).

A stamped, accepted copy of the label is enclosed for your records.

Sincerely,



Kimberly Nesci, Chief  
Microbial Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)

Enclosures (2):

- SOYACYST™ ST Plus Stamped, Accepted Label
- A-79 Enclosure

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(Master)

**SOYACYST™ ST Plus**  
[Alternate Brand Name: Clariva™ pn]

Nematicide

A biological seed treatment product for protection against listed nematodes on soybeans and sugarbeets

Active Ingredient:	
<i>Pasteuria nishizawae</i> – Pn1*	15.000%
Other Ingredients:	85.000%
Total:	100.000%

\* Contains at least  $1.0 \times 10^{10}$  spores per mL or  $3.8 \times 10^{13}$  spores per gal.

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See additional precautionary and first aid statements in booklet [on label].

EPA Reg. No. 100-1524

EPA Est. XXXX

SCP 1524

Net Contents

[Batch code to be marked directly on containers that are nonrefillable. Batch code not required for refillable containers.]

**ACCEPTED**

**JUL 18 2014**

Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for  
the pesticide registered under  
EPA Reg. No. 100-1524

<b>FIRST AID</b>	
<b>If inhaled</b>	<ul style="list-style-type: none"><li>• Move person to fresh air.</li><li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible.</li><li>• Call a poison control center or doctor for further treatment advice.</li></ul>
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
<b>HOT LINE NUMBER</b> For 24-Hour Medical Emergency Assistance (Human or Animal) Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call <b>1-800-888-8372</b>	

**PRECAUTIONARY STATEMENTS**

**Hazards to Humans and Domestic Animals**

**CAUTION**

Harmful if inhaled. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse.

**Personal Protective Equipment (PPE)**

**Applicators and other handlers must wear:**

- Long-sleeved shirt and long pants
- Shoes plus socks

Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

**USER SAFETY RECOMMENDATIONS**

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. If gloves are worn, wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

**Environmental Hazards [less than 5 gallons]**

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate.

**Environmental Hazards [greater than or equal to 5 gallons]**

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA.

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**CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY**

**NOTICE:** Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: ~~(1) this warranty does not extend to the use of the product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use.~~ **TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

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## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For use only in commercial seed treatment equipment. Not for use in hopper box, planter box, slurry box, or other on-farm seed treatment applications.

Do not use this product until you have read the entire label.

Keep unprotected persons out of treatment areas until seeds have dried or been packaged.

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### PRODUCT INFORMATION

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This product contains a biological nematicide for protection against the following nematodes:

**Soybean Cyst Nematode**  
**Sugarbeet Cyst Nematode**

*Heterodera glycines*  
*Heterodera schachtii*

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### FOR USE AS A SEED TREATMENT

Treatment of highly mechanically scarred or damaged seed, or seed known to be of low vigor and poor quality, except for the purpose of curative control of existing disease pests, may result in reduced germination and/or reduction of seed and seedling vigor. Treat a small quantity of seed using equipment similar to that planned for treating the total seed lot. Conduct germination tests on a small portion of seed before committing the total seed lot to a selected seed treatment. Due to seed quality, crop or variety sensitivity, and seed storage conditions beyond the control of manufacturer, no claims are made to guarantee the germination of carry-over seed or propagating material for all crop seed.

To achieve improved application coverage to the seed, dilute SOYACYST™ ST Plus with water and apply directly to dry seed or mix with inoculants and/or other registered seed treatment coatings (e.g., colorants, polymers, etc.), insecticides and fungicides. Do not mix SOYACYST™ ST Plus with any product containing a label prohibition against such mixing. When tank-mixing with any other registered seed treatment insecticide and/or fungicide, always read and follow all use directions, restrictions, and precautions of both SOYACYST™ ST Plus and the tank mix partner(s). The resulting tank mix must be in accordance with the more restrictive label limitations and precautions. Do not exceed label dosage rates.

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NOTE: This product does not contain dye. All seed treated with this product must be colored with an EPA-approved dye or colorant of a suitable color to prevent accidental use as food for humans or feed for animals.

The Federal Seed Act requires that bags containing seed treated with this product shall be labeled with the following information: "This seed has been treated with *Pasteuria nishizawae* - Pn1. Do not use for food, feed or oil purposes."

### **SOYBEAN**

For protection against soybean cyst nematode, apply 0.9 to 33.8 fl oz of SOYACYST™ ST Plus per 100 lb (25 to 1000 mL per 45.4 kg) of soybean seed.

### **SUGARBEET**

For protection against sugarbeet cyst nematode, apply 0.034 to 1.35 fl oz (1.0 to 40 mL) of SOYACYST™ ST Plus product per unit (100,000 seeds) of sugarbeet seed.

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage or disposal.

**Pesticide Storage**

Store between a range of 32°F to 100°F. Reclose container of unused portions of SOYACYST™ ST Plus.

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes.

**Pesticide Disposal**

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**Container Handling [less than or equal to 5 gallons]**

**Nonrefillable container.** Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

**Container Handling [greater than 5 gallons]**

**Nonrefillable container.** Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

**Container Handling [greater than 5 gallons]**

**Refillable container.** Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the person refilling. To clean the container before final

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disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

**CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER!**

SOYACYST™ [Clariva™], the ALLIANCE FRAME, the SYNGENTA Logo, and the PURPOSE ICON are Trademarks of a Syngenta Group Company.

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For non-emergency (e.g., current product information), call  
Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:  
Syngenta Crop Protection, LLC  
P. O. Box 18300  
Greensboro, North Carolina 27419-8300

SCP 1524

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(Non-detachable Container Label)

**SOYACYST™ ST Plus**

[Alternate Brand Name: Clariva™ pn]

Nematicide

A biological seed treatment product for protection against listed nematodes on soybeans and sugarbeets

Active Ingredient:

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Other Ingredients: ..... 85.000%

Total: ..... 100.000%

\* Contains at least  $1.0 \times 10^{10}$  spores per mL or  $3.8 \times 10^{13}$  spores per gal.

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See additional precautionary and first aid statements in booklet.

EPA Reg. No. 100-1524

EPA Est. XXXX

SCP 1524

Net Contents

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<b>FIRST AID</b>	
<b>If inhaled</b>	<ul style="list-style-type: none"><li>• Move person to fresh air.</li><li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible.</li><li>• Call a poison control center or doctor for further treatment advice.</li></ul>
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
<b>HOT LINE NUMBER</b> For 24-Hour Medical Emergency Assistance (Human or Animal) Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call <b>1-800-888-8372</b>	

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Harmful if inhaled. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse.

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**Applicators and other handlers must wear:**

- Long-sleeved shirt and long pants
- Shoes plus socks

Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

**USER SAFETY RECOMMENDATIONS**

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- Remove PPE immediately after handling this product. If gloves are worn, wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

**Environmental Hazards [less than 5 gallons]**

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate.

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Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA.

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## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

### **Pesticide Storage**

Store between a range of 32°F to 100°F. Reclose container of unused portions of SOYACYST™ ST Plus.

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes.

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equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

**CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER!**

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Manufactured for:  
Syngenta Crop Protection, LLC  
P. O. Box 18300  
Greensboro, North Carolina 27419-8300

SCP 1524

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